K101926

DEC 2 0 2011

Attachment B2

510(k) Summary

1. Submitter Information

Company name	TaiDoc Technology Corporation
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Date Prepared	July 7th, 2010

2. Name of Device

Trade/Proprietary Name	FORA D40d Blood Glucose plus Blood Pressure Monitoring System and FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring System
Common Names	Blood glucose and Blood Pressure test system
Product Code	NBW, CGA, DXN
Classification Panel	Clinical Chemistry (75) ; Cardiovascular
Regulations	Class II 21 CFR 862.1345 / 21 CFR 870.1130

3. Predicate Device

Trade/Proprietary Name:	TD-3252 Blood Glucose plus Blood Pressure Monitoring System
Common/Usual Name:	Blood glucose and blood pressure test system
Submitter	TaiDoc Technology Corporation
510 (k) Number	K091555

4. Device Description

The FORA D40d Blood Glucose plus Blood Pressure Monitoring System FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring System consists of one monitor, test strip, control solution, and a pressure cuff. The proposed device has been designed, tested, and demonstrated to work together as a system to produce accurate blood glucose test results and blood pressure measurements.

The proposed device contains speaking function which offers step-by-step audio instructions to help users perform a glucose test or take a blood pressure measurement.

5. Intended Use

FORA D40d for single patient use

The FORA D40d Blood Glucose plus Blood Pressure Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, and upper arm. This system is intended to be used by a single person and should not be shared.

The FORA D40d Blood Glucose plus Blood Pressure Monitoring System is intended for self testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing should be done only during steady – state times (when glucose is not changing rapidly).

The FORA D40d Test Strips are for use with the FORA D40d Blood Glucose plus Blood Pressure Monitoring System to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, and upper arm.

This system is also intended to be used to measure non-invasively the systolic and diastolic blood pressure and pulse rate of an adult individual at home. The blood pressure is measured by using an inflatable cuff wrapped around the arm.

This system contains speaking function, but is not intended for use by the visually impaired.

FORA Wisdom D40d for multiple patients use

The FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary

whole blood samples drawn from the fingertips, palm, forearm, and upper arm. This system is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. This system is only used with single-use auto-disabling lancing devices.

The FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing such as the palm, forearm, and upper arm should be done only during steady – state times (when glucose is not changing rapidly).

The FORA Wisdom D40d Test Strips are for use with the FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring System to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, and upper arm.

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6. Comparison to Predicate Device

For blood glucose, consumer study was performed to evaluate the accuracy at fingertip and alternative sites including palm, forearm and upper arm compared to YSI-2300. For blood pressure, a clinical study was performed compared to the reference method according to the requirements of ANSI/AAMI SP10.

The FORA D40d and FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring Systems are substantially equivalent to the predicate device, TD-3252 Blood Glucose plus Blood Pressure Monitoring System (K091555).

7. Performance Studies

To evaluate the system accuracy of FORA D40d and FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring System, the consumer study was performed according to ISO 15197 and other tests performed according to ANSI/AAMI SP10. Results show that the device met the requirements of ISO 15197 and ANSI/AAMI SP10, and is safe during

the use. It is substantially equivalent to the predicate device with the same effectiveness and safety.

The proposed device met the requirements of IEC/EN 60601-1:1995, IEC/EN 60601-1-2:2001, EN 61326-1:2006, IEC/EN 61010-1:2001 and IEC/EN 61010-2-101:2002. It complies with Part 15 of FCC rules. Software validation was also performed to verify and validate the system works functionally.

8. Conclusion

The FORA D40d and FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring Systems demonstrate satisfactory performance and are suitable for its intended use. The FORA D40d and FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring Systems are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

TAIDOC TECHNOLOGY CORPORATION
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WUGU DISTRICT
NEW TAIPEI CITY
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Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

DEC 20 2011

Re: k101926
Trade Name: FORA D40d Blood Glucose plus Blood Pressure Monitoring System
FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA, DXN
Dated: December 2, 2011
Received: December 12, 2011

Dear Ms. Ko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: k101926
Device Name: FORA D40d Blood Glucose plus Blood Pressure Monitoring System

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This system contains speaking function, but is not intended for use by the visually impaired.

Prescription Use _____ AND/OR Over the Counter Use ___X___
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K101926

Indications for Use

510(k) Number: k101926
Device Name: FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring System

Indications for Use:

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